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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

CARMEN OTERO and ABBEY LERMAN, as individuals and on behalf of other members of the general public similarly situated,

Plaintiffs,

vs.

ZELTIQ AESTHETICS, INC., a Delaware corporation; and DOES 1-10, inclusive,

Defendants.

Case No. 2:17-cv-03994-DMG (MRWx)

Hon. Dolly M. Gee

PLAINTIFFS' OPPOSITION TO DEFENDANT ZELTIQ AESTHETICS, INC.'S MOTION TO DISMISS FIRST AMENDED CLASS ACTION COMPLAINT

Date: September 22, 2017
Time: 9:30 a.m.
Courtroom: 8C

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I. INTRODUCTION

Plaintiffs Carmen Otero and Abbey Lerman ("Plaintiffs") filed their First Amended Complaint ("FAC") seeking to hold Defendant Zeltiq Aesthetics, Inc. ("Defendant") liable for unlawful and deceptive labeling and related advertising of its "CoolSculpting" medical devices pursuant to California's consumer protection statutes – the Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200 *et. seq.*) ("UCL"), False Advertising Law (Cal. Bus. & Prof. Code §§ 17500 *et seq.*) ("FAL") and Consumer Legal Remedies Act (Cal. Civil Code §§ 1770 *et seq.*) ("CLRA"). Plaintiffs' claims are predicated on Defendant's false, misleading and deceptive marketing practices which lead consumer to believe that they were purchasing medical treatments that have gone through the rigorous FDA pre-market approval process, with all the safety and efficacy that implies. In actuality, however, the CoolSculpting devices have only received the far less rigorous 510(k) premarket notification clearance, which merely determines that the devices are substantially equivalent to a pre-existing device marketed before the enactment date of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Indeed, the FDA itself warns against such misrepresentations by stating that representations "that create[s] an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. §807.97. Thus, Defendant's representations implying that the CoolSculpting devices have received FDA approval violate California's Sherman Law, which preclude holds that "[i]t is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390.

Here, Defendant has filed a motion to dismiss Plaintiffs' FAC based on various grounds. For the reasons stated below, Defendant's Motion should be denied.

Defendant's preemption argument fails in many respects. First, the Medical Device Amendment ("MDA") explicitly exempts Plaintiffs' state law claims for unfair and deceptive business practices. *See* 21 C.F.R. §808.1 (d)(1) (exempting "unfair trade practices in which the requirements are not limited to devices). The MDA also exempts state law claims "that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. §808.1(d)(2). Here, Plaintiffs' claims under the UCL, FAL and CLRA are equal to, or substantially identical to, requirements imposed under the act. Second, Defendant's preemption argument directly contradicts governing United States Supreme Court authority in *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), which concluded that federal law does not preempt claims stemming from medical devices that were cleared through the 510(k) process, as opposed to Pre-Market Approval ("PMA"). Finally, under applicable California authority, because Plaintiffs allege violations of California's Sherman Law, are not direct violations of the Food, Drug, and Cosmetic Act ("FDCA"), they are not preempted.

Similarly, despite Defendant's assertions, Plaintiffs have sufficiently alleged their claims under the California Consumer Legal Remedies Act (Cal. Civil Code §§ 1770 *et seq.*) ("CLRA"), Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200 *et. seq.*) ("UCL"), and False Advertising Law (Cal. Bus. & Prof. Code §§ 17500 *et seq.*) ("FAL"). For example, Plaintiffs sufficiently allege violation of the UCL under the unlawful prong by alleging that Defendant has violated California's Sherman Law.

Moreover, Plaintiffs have properly alleged that Defendant has a duty to disclose that the CoolSculpting procedure has not received FDA approval, in direct contrast to the representations and inferences contained in Defendant's marketing and advertising of the device. Despite Defendant's assertion, current authority does not require that Defendant's omission relate to safety concerns that pose unreasonable safety hazards. Here, where Defendant makes a partial representation

that the device has been FDA cleared, but also suppresses material facts that FDA clearance is a dramatically different process than FDA approval and does not evaluate the device for safety and efficacy, Defendant has an obligation to disclose.

In addition, UCL, FAL and CLRA claims may be based on deceptive, although technically true, statements. The standard is whether the representations tend to mislead or deceive the reasonable consumer. Here, Plaintiffs sufficiently allege that Defendant's representations tend to mislead the reasonable consumer into believing that the CoolSculpting device has obtained FDA approval as to its safety and efficacy when, in fact, Defendant only obtained "clearance" under the 510(k) process. Such statements have the capacity, likelihood and tendency to deceive or confuse the public, and are therefore proper bases for UCL, FAL and CLRA claims. The fact that Plaintiffs allege that Defendant controls the direct and digital marketing of the CoolSculpting procedures, in concert with its clients who purchase the devices, is sufficient to allege Defendant's liability with respect to these marketing claims.

As to Defendant's remaining arguments in the motion to dismiss – failure to plead with particularity under Rule 9(b), standing etc.. – such arguments have all been routinely rejected by the Ninth Circuit's district courts when addressing similar arguments raised by defendants. The Court should, respectfully, reject those arguments here as well.

For these reasons, Defendant's Motion to Dismiss should be denied in its entirety.

II. THE STANDARDS FOR RULING ON A RULE 12(B)(6) MOTION TO DISMISS

Pursuant to Rule 12(b)(6), a plaintiff must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007). A claim has "facial plausibility" if the plaintiff pleads facts that "allow [ ] the court to draw the reasonable inference that the defendant is liable for

the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). In considering the motion, the court must "accept as true all of the factual allegations set out in plaintiff's complaint, draw inferences from those allegations in the light most favorable to plaintiff, and construe the complaint liberally." *Rescuecom Corp. v. Google, Inc.*, 562 F.3d 123, 127 (2nd Cir. 2009); *Mediacom Southeast LLC v. BellSouth Telecommunications, Inc*., 672 F.3d 396, 400 (6th Cir. 2012). Further, "[i]n ruling on a motion pursuant to Fed. R. Civ. P. 12(b)(6), the duty of a court 'is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *DiFolco v. MSNBC L.L.C.*, 622 F.3d 104, 113 (2d Cir. 2010) (quoting *Cooper v. Parsky*, 140 F.3d 433, 440 (2d Cir. 1998)).

Here, if the Court dismisses any portion of the Complaint, Plaintiffs respectfully request leave to amend. *DeSoto v. Yellow Freight Sys*., 957 F.2d 655, 658 (9th Cir. 1992) (leave to amend is only properly denied "where the amendment would be futile").

III. PLAINTIFFS' CLAIMS ARE NOT PREEMPTED

The Supreme Court has cautioned that "courts should not lightly infer preemption." *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 491, 107 S. Ct. 805, 93 L. Ed. 2d 883 (1987). Instead, "and particularly in those [cases] in which Congress has 'legislated ... in a field which the States have traditionally occupied,' we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485. Thus, "[t]here is a presumption against implied preemption of State law in areas traditionally regulated by the states." *Chamberlan v. Ford Motor Co.*, 314 F.Supp.2d 953, 958 (N.D. Cal. 2004).[1]

[1] Fraud and unfair business practices are areas traditionally regulated by the States. *Chamberlan,* 314 F. Supp. 2d at 959 (*citing Florida Lime and Avocado Growers,* (Continued...)

A. Plaintiffs' State Law Claims Are Not Preempted Because They Relate to Claims of "Unfair Trade Practices…Not Limited to [Medical] Devices"

The MDA provides that state law claims are preempted only if they impose requirements that are "different from, or in addition to" a federal regulation or requirement and "relate[s] to safety and effectiveness" of the medical device. 21 U.S.C. §360k(a). Stated differently, "the scope of preemption is limited to instances where there are *specific* FDA requirements applicable to a *particular* device." *Comm. of Dental Amalgam Mfrs. And Distribs. V. Stratton,* 92 F.3d 807, 812 (9th Cir. 1996)(citation omitted) (emphasis in original). In practice, the only medical devices subject to MDA preemption are those that undergo the pre-market approval ("PMA") process, and not those who undergo the pre-market notification process. *Lohr,* 518 U.S. at 501.

State law claims alleging "unfair trade practices in which the requirements are not limited to devices" cannot be preempted by the MDA. 21 C.F.R. §808.1(d)(1). This rule directly applies to Plaintiffs' UCL, FAL and CLRA claims. The UCL and FAL are "unfair trade practices" statutes of general applicability, and are not "limited to [medical] devices." *See, e.g., Cel-Tech Comms. v. Los Angeles Cellular Tel. Co.,* 20 Cal.4th 163, 180 (1999) (holding that the UCL's reach is "sweeping, embracing anything that can properly be called a business practice and that at the same time is forbidden"); *Comm. Of Dental Amalgam Mfrs., supra,* 92 F.3d at 813 (reversing district court's granting of summary judgment on preemption grounds, reasoning that Proposition 65, a law requiring businesses to warn consumers of chemicals known to

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Inc. v. Paul, 373 U.S. 132, 145–46, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963); *California v. ARC Am. Corp*., 490 U.S. 93, 101, 109 S. Ct. 1661, 104 L. Ed. 2d 86 (1989)).

pose public health risks, was a "state law of general applicability" and "not directed at any product or industry").

Defendant's preemption argument directly contradicts governing United Supreme Court authority in *Lohr, supra,* 518 U.S. 470. There, the Supreme Court held that state laws and statutes of general applicability such as state consumer fraud statutes are not preempted by the MDA. State requirements are "only" preempted when the "FDA has established " ' specific counterpart regulations or … other specific requirements applicable to a particular device.' " *Id.* at 498 (quoting 21 C.F.R. §808.1(d)).

B. 510(k) Clearance Is Not A Basis For Preemption

The FDA regulates the introduction of medical devices into interstate commerce, pursuant to the MDA. 90 Stat. 539. Under the MDA, the FDA can review products and allow them to go to market via two different procedures: PMA or 510(k) Clearance.

The first procedure is the rigorous PMA process, generally applicable to all new Class III devices (and some Class II products). PMA requires manufacturers to provide the FDA with proof that the device is both safe and effective, through an exhaustive and comprehensive device-specific review. 21 U.S.C. §360e. Under the PMA process, the FDA only grants approval when there is a reasonable assurance of the device's safety and effectiveness. *Id.*

The second procedure, the "pre-market notification" or "510(k) Clearance" process, allows a manufacturer to market a device that the FDA determines is "substantially equivalent" to another product that was previously cleared or approved by the FDA. 21 U.S.C. §360c(i)(1); 21 U.S.C. §807.92; *Lohr*, 518 U.S. at 478. "The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in an average of only 20 hours." *Lohr*, 518 U.S. at 479. "The attraction of substantial equivalence is clear. 510k notification requires little information,

rarely elicits a negative response from the FDA, and gets processed very quickly. *Id.* Unlike the PMA process, the "FDA does not 'require' that a device allowed to enter the market as a substantial equivalent [through the 510k process] take any particular form for any particular reason.'" *Id.* at 493. Due to these differences, 510(k) clearance does not constitute "approval" of a device or its labeling and "any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. §807.97.

The Supreme Court explained in *Lohr* that the regulatory path a medical device takes – e.g., 510(k) clearance versus PMA – is critical to the preemption analysis. In *Lohr*, the Court held that state law design defect claims against a manufacturer of pacemakers, which were cleared through the 510(k) process, were not preempted. 518 U.S. at 494. The Court contrasted 510(k) clearance with PMA, observing that the abbreviated, expedited 510(k) process did not "require … a device substantially equivalent to [an existing one], to be marketed without running the gauntlet of the PMA process." *Id.* PMA is "by no means comparable" to 510(k) clearance. *Id.* at 478-479.

> There is no suggestion in either the statutory scheme or the legislative history that the §510(k) exemption process was intended to do anything . . . [to exclude] the possibility that the manufacturer of the device would have to defend itself against state-law claims."

Lohr, 518 U.S. at 494; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

C. Plaintiffs' Claims Are Predicated Upon Violations of California's Sherman's Law and Are Therefore Not Preempted

Although the Sherman Law incorporates the regulations set forth in the FDCA, it expressly states that it is incorporating the federal regulations as the "new drug and new device application regulations of this state." Cal. Health & Safety Code §

110110(a).[2] Accordingly, when a plaintiff sues under the Sherman Law, he is not "suing *because* [defendant's labeling] violates the FDCA," *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), but rather because the defendant's labeling violates California's labeling laws. *Kane v. Chobani*, 2013 WL 3703981, *14 (N.D. Cal. July 12, 2013). Moreover, the Sherman Law specifically provides that "[i]t is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390.

Indeed, the FDA addressed many issues related to federal preemption in its ruling responding to the State of California's Application for Exemption from Federal Preemption of State Medical Device Requirements. Medical Devices; California Application for Exemption From Federal Preemption of State Medical Device Requirements, 45 Fed. Reg. 67321-01. In its ruling, the FDA responded to specific questions of federal preemption within the Sherman Law. The FDA held that Cal. Health & Safety Code §110390 (Chapter 4, Article 3 of the Sherman Law) relates to "general requirements not applicable to specific devices" and is therefore not preempted "unless they are applied to a specific device in such a way as to establish requirements that are different from or in addition to adverting requirements established by the FDA for the device." *Id.* As alleged throughout Plaintiffs' complaint, Defendant has violated Cal. Health & Safety Code § 110390 by disseminating false and misleading statements related to its CoolSculpting procedure. Indeed, by creating an impression that the device has been officially approved because of the premarket notification regulations, Defendant's representations are misleading. 21 CFR § 807.97. Thus, Plaintiffs are not suing under the unlawful

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[2] While Cal. Health & Safety Code § 110110(a) refers to regulations relating to devices that apply for premarket approval, Section 111550 defines "new devices" to include devices that are "reported under Section 510(k) of the federal act (21 U.S.C. or 360(k))[.]" Cal. Health & Safety Code § 111550.

prong of the UCL *because* Defendant's conduct violates the FDCA; rather, they are suing because Defendant's conduct allegedly violates California's Sherman Law, which could have imposed the exact same regulations. *Gustavson v. Wrigley Sales Company*, 961 F.Supp.2d 1100, 1119 (N.D. Cal. 2013).

Moreover, it is well-established that "the FDCA does not preempt state laws that allow consumers to sue manufacturers that label or package their products in violation of federal law." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757 (9th Cir. 2015). Instead, it preempts any state law that imposes a requirement "that is different from or in addition to, or that is otherwise not identical with" a requirement of the FDCA or certain related federal statutes. Accordingly, plaintiffs can escape the preemptive force of the FDCA if their claims seek to impose requirements that are identical to those imposed by the FDCA. Here, Plaintiffs' state law claims allege that Defendant has disseminated false and misleading advertisements to imply that the CoolSculpting procedure has been approved by the FDA as safe and effective. FAC ¶¶1-14, 33-54. These allegations seek to enforce identical requirements as those imposed by the FDCA: that companies may not create "an impression of official approval of a device because of complying with the premarket notification regulations" as such an impression would be misleading. 21 C.F.R. §807.97; *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.2d 899, 993 (1994) ("when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements.").

D. The Cases Defendant Relies on Are Inapposite

The cases relied on in Defendant's Motion are inapposite to the case at bar. *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) and *Buckman Co. v. Plaintiffs' Legal. Comm.*, 531 U.S. 341 (2001) do not apply to this matter.

In *Buckman*, the plaintiffs alleged the defendant made fraudulent representations to the FDA, which led to the FDA's approval of medical devices that

caused injuries to the plaintiffs. *Buckman*, 531 U.S. at 343. The Supreme Court concluded, "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348. Plaintiffs' claims, however, are not based on fraud-on-the-FDA as Plaintiffs do not allege that Defendant made fraudulent representations to the FDA. Instead, Plaintiffs' claims are based on fraud-on-the-consumer – that Defendant's labels were misleading and are therefore not preempted.

In *Perez*, there was no independent California law imposing a duty on manufacturers of medical devices to "affirmatively tell patients when medical devices have not been approved for a certain use." 711 F.3d at 1118-19. Thus, Perez's fraud-by-omission claim existed only by virtue of the FDCA disclosure requirements. *Id.* at 1119. "Here, while Plaintiffs' Sherman Law claim draws its standards from federal labeling requirements, it is rooted in and 'exist[s] by virtue' of California law." *Kane*, 2013 WL 3703981 at *15.

Indeed, cases that have addressed claims that a company has alluded to FDA approval, either directly or indirectly (as here), have found that the claims are not preempted. For example, in *Innovative Health Solutions, Inc., v. DyAnsys, Inc.*, 2015 WL 2398931 (N.D. Cal. May 19, 2015), the Court held that plaintiff's UCL, FAL, and Lanham Act claims were not preempted. There, plaintiff alleged that consumers would be misled by the defendant misrepresenting that its product had FDA approval. *Id.* at *7 ("The Court finds that to the extent plaintiff alleges that defendants have falsely represented that they obtained FDA approval for their products, those claims are not precluded or preempted."). Similarly, here, Plaintiff alleges that consumers would be misled by Defendant misrepresenting that it has

FDA approval by citing to the FDA clearance. In *Par Sterile Products, LLC v. Fresenius Kabi USA LLC,* 2015 WL 1263041 (N.D. Ill. Mar. 17, 2015), the court held that the plaintiff's state law false advertising claims were not preempted where the defendant

> injuriously misrepresents its product as FDA-approved by offering it for sale in certain marketing channels alongside FDA-approved generic drugs. Whether Fresenius is actually deceiving consumers…by doing so remains in question at this early stage of the proceedings, but the dispute is of the sort with which the Lanham Act is concerned to the extent it involves deception of consumers as to the fact of whether a product carries the imprimatur of FDA approval, not whether the product is safe and effective enough to be approved by the FDA.

Id. at *4.

Here, as in *Par Sterile,* Plaintiffs do not allege that the CoolSculpting procedure is not safe and effective enough to be approved by the FDA. Instead, Plaintiffs allege that Defendant's representations involve deception of consumers as to the fact of whether the CoolSculpting procedure carries the imprimatur of FDA approval. As such, Plaintiffs' claims are not precluded.

IV. PLAINTIFFS HAVE SUFFICIENTLY PLED THEIR CLRA, UCL AND FAL CLAIMS

The UCL prohibits three types of business acts or practices: unlawful, unfair and fraudulent. Cal. Bus. & Prof. Code §17200. Each part of §17200's definition of unfair competition operates separately from each other part. *See Planned Parenthood Federation of America, Inc. v. Center for Medical Progress,* 2016 WL 5946858 (N.D. Cal. 2016) (Each prong of the UCL - unlawful, unfair, and fraudulent - creates a separate and distinct basis for liability and one act can be alleged to violate any or all the UCL prongs.); *Cornejo v. Ocwen Loan Servicing, LLC, et al.,* 151 F. Supp. 3d 1102 (E.D. Cal. Dec. 18, 2015) (same).

Under the "unlawful" prong, the UCL permits a cause of action to be brought if a practice violates some other law. In effect, the "unlawful" prong

makes a violation of the underlying law a *per se* violation. *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.,* 20 Cal.4th 163, 180 (1999). A plaintiff proceeding under the "unlawful" prong need only plead facts to show it is plausible the defendant broke the law because the legislature has already determined the conduct to be "unfair" by virtue of legislative prohibition." *Swearingen v. Yucatan Foods, L.P.*, 24 F. Supp. 3d 889, 900 (N.D. Cal. 2014). Here, Plaintiff has adequately alleged an unlawful UCL claim based on Defendant's violation of the Sherman Law, as described below.

To establish liability under the "fraudulent" prong of the UCL, the FAL, and CLRA, "it is necessary only to show that members of the public are likely to be deceived." *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009) (internal quotations and citations omitted); *see also Freeman v. Time, Inc*., 68 F.3d 285, 289 (9th Cir. 1995) ("[T]he false or misleading advertising and unfair business practices claim must be evaluated from the vantage of a reasonable consumer."); *Morgan v. AT&T Wireless Services, Inc*., 177 Cal. App. 4th 1235, 1256 (2009) ("[t]he determination as to whether a business practice is deceptive is based on the likely effect such [a] practice would have on a reasonable consumer.")[3] Unlike common law fraud, which requires proof of falsity, scienter, and actual reliance, it is not necessary for a plaintiff to prove that a fraudulent deception under the UCL, FAL or CLRA was actually false, known to be false by the perpetrator, or reasonably relied upon by a victim who incurs damages. *Id*.[4]

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[3] Federal courts generally refrain from resolving deceptiveness under the CLRA, UCL and FAL at the pleading stage. *See e.g., Williams v. Gerber Products Co.*, 552 F.3d 934, 938 (9th Cir. 2008) ("Federal courts 'have recognized that whether a business practice is deceptive will usually be a question of fact not appropriate for decision on a [motion to dismiss].'"). Same with California state courts. *See Linear Technology Corp. v. Applied Materials, Inc*., 152 Cal. App. 4th 115, 134–35 (2007).

[4] *See also Clemens v. DaimlerChrysler Corp*., 534 F.3d 1017, 1025–26 (9th Cir.

(Continued...)

Plaintiffs need only demonstrate that they have sufficiently alleged one of the three prongs of the UCL. *Arevalo v. Bank of America Corp.,* 850 F. Supp.2d 1008, 1023 (March 29, 2011) (denying motion to dismiss after finding that plaintiff sufficiently stated a claim under the unlawful prong of the UCL and rejecting defendant's assertion that all three prongs of the UCL needed to be adequately pleaded).

A. Plaintiffs Adequately Plead Zeltiq's Duty to Disclose

Although "a claim may be stated under the CLRA in terms constituting fraudulent omissions, to be actionable the omission must be contrary to a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose." *Daugherty v. American Honda Motor Co.,* 144 Cal.App.4th 824, 834 (2006). Courts have generally found a broader duty to disclose in cases where the defendant made affirmative representations that are contrary to the undisclosed information. *Id.* at 834–37. Here, Plaintiffs allege that Defendant's misleadingly infer that the CoolSculpting procedure received FDA approval, when, in fact, the device only receives the less rigorous 501(k)clearance.

Defendant argues for an initial limitation on the scope of any duty to disclose, asserting that for an omission to be actionable under the CLRA, UCL or FAL, it must relate to "safety concerns that pose an 'unreasonable safety hazard.'" Dkt. No. 17 at 12. The California Court of Appeal, however, clarified that this is a misreading of California law. In *Rutledge v. Hewlett–Packard Co.,* 238 Cal.App.4th 1164, 1174 (2015), the court distinguished the authority relied on in the cases relied upon by Defendant: "Both *Daugherty* and *Bardin* do address disclosure of defects related to safety concerns in the context of CLRA and UCL claims. However, neither *Daugherty* nor *Bardin* preclude a duty to disclose material information

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2008) ("Unlike a common law fraud claim, a UCL fraud claim requires no proof that the plaintiff was actually deceived.")

known to a manufacturer and concealed from a consumer." The court emphasized that "[t]he *Bardin* court did *not* hold that a defect must be related to a safety concern to be material for purposes of fraudulent omission." *Id.* (emphasis added). Thus, current applicable law precludes Defendant's contentions that Plaintiffs must allege an omission related to a serious safety concern. *In re: Lenovo Adware Litigation*, No. 15-MD-02624-RMW, 2016 WL 6277245, at *13 (N.D. Cal., Oct. 27, 2016) ("As explained in *Rutledge*, the California Court of Appeal's earlier *Daugherty* decision does not explicitly foreclose the possibility of a duty to disclose absent an affirmative representation or safety concern. Accordingly, the court declines to dismiss plaintiffs' UCL and CLRA claims for failure to allege either an affirmative misrepresentation or a safety concern."); *Norcia v. Samsumg Telecommunications America, LLC,* 2015 WL 4967247 (N.D. Cal. Aug. 20, 2015) (holding that *Rutledge* precluded a finding that a duty to disclose only exists where there is a safety concern).

"Under California law, there are four circumstances in which an obligation to disclose may arise: (1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material facts." *Asghari v. Volkswagen Grp. of Am., Inc.*, 2013 WL 9885046, at *15 (C.D. Cal. Nov. 4, 2013). "Under this standard, absent a fiduciary relationship between the parties, the facts the defendant knows and conceals must be material." *Id.*

"A misrepresentation is judged to be 'material' if a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question," and, as such, "materiality is generally a question of fact unless the fact misrepresented is so obviously unimportant that the jury could not reasonably find that a reasonable man would have been influenced

by it." *In re Tobacco II Cases,* 46 Cal.4th 298, 327 (2009); *Kimberly-Clark Corporation,* 2015 WL 4264638, at *7 (C.D. Cal., July 10, 2015). Here, Plaintiffs' FAC adequately alleges that FDA approval of the CoolSculpting procedure is material. FAC ¶17, 22, 60, 72, 73, 91, 92; s*ee also SEC v. Schiffer,* 1998 WL 307375, at *2 (S.D.N.Y. June 11, 1998) (false representations regarding FDA approval are material).

A party may be held liable for an omission if there was the "suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact." Cal. Civ. Code § 1710. A duty to disclose arises "when the defendant makes partial representations but also suppresses some material fact." *Falk v. Gen. Motors Corp.*, 496 F.Supp.2d 1088, 1095 (N.D. Cal. 2007) (citation omitted). Thus, if Plaintiffs have adequately alleged that Defendant's products are represented to be FDA cleared, but FDA clearance has no actual impact on the procedure's safety and effectiveness, the omission of that latter fact would give rise to an actionable omission claim. *Hadley v. Kellogg Sales Company,* 2017 WL 3453391, at *29 FN 4 (N.D. Cal., Aug. 10, 2017); *see e.g. Klein v. Chevron U.S.A.*, 202 C.A.4th 1342, 1351 (2012) (holding a duty to disclose existed because the defendant made partial representations that gasoline was sold in "gallons" but omitted that consumers received less than a gallon of fuel after the effects of thermal expansion); *GeoData Systems Management, Inc. v. American Pacific Fabricators, Inc.*, 2016 WL 6562064 (C.D. Cal. Apr. 21, 2016) (holding duty to disclose properly alleged when defendants partially disclosed they held a patent, but omitted that the patent was only owned by one defendant). Here, Plaintiffs make exactly these allegations, and allege that they relied on Defendant's partial representations implying that the CoolSculpting treatments were approved by the FDA. FAC ¶16-22; 33-54.

B. UCL, FAL and CLRA Claims May Be Based on Deceptive But Technically True Statements

A claim that a business practice is (or was) "fraudulent" under the UCL, FAL, or CLRA can be based upon representations that deceive because they are untrue as well as representations that may be accurate on some level but nonetheless tend to mislead or deceive. *Morgan,* 177 Cal. App. 4th at 1255; *Williams,* 552 F. 3d at 938 ("The California Supreme Court has recognized 'that these laws prohibit 'not only advertising which is false, but also advertising which [,] although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public'"). As such, "[a] perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under the UCL[,]" FAL, and CLRA. *Id.* at 1255; *In re Ferrero Litigation,* 794 F.Supp.2d 1107, 1115 (S.D. Cal. June 30, 2011) ("A statement may be deceptive and actionable under the UCL, FAL, and CLRA even though it is truthful.").

Moreover, "[t]he determination as to whether a business practice is deceptive is based on the likely effect such practice would have on a reasonable consumer." *Klein v. Chevron U.S.A., Inc.,* 202 Cal.App.4th 1342, 1380-1381 (2012). Because California courts "have recognized that whether a business practice is deceptive will usually be a question of fact," it is a "rare situation in which granting a motion to dismiss is appropriate." *Williams, supra*, 552 F.3d at 938-939.

The case Defendant relies on, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) is inapplicable to Plaintiffs' UCL, FAL and CLRA claims. *PhotoMedex* involved efforts to bring Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, claims for alleged FDCA violations. There, however, the claim involved re-approval of a medical device and was based on the contention that a marketed laser varied enough from a FDA cleared laser as to require 510(k) clearance. *Id.* Determining whether new 510(k) clearance was required under the FDA would have required the court to interpret the provisions of the FDCA. *Id.* Indeed, as the court in *PhotoMedex* stated, if "it was clear that an affirmative statement of

approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries…as a result of a false assertion that approval had been granted[.]" *PhotoMedex*, 601 F.3d at 924-25. Thus, *PhotoMedex* specifically provides for the claims alleged in Plaintiffs' FAC.

C. Defendant Controls the Marketing of the CoolSculpting Procedure

Plaintiffs' FAC alleges that Defendant provides support and training to the direct purchasers of the CoolSculpting system, including "on-location training to clinic and spa providers, and offers more intensive training to providers at 'CoolSculpting University.'" FAC ¶ 44. Plaintiffs further allege that Defendant employs a team of "Practice Development Managers" to "assist[] practices to market CoolSculpting to patients" including "branding, grassroots initiatives and digital marketing tactics." *Id.* Thus, Plaintiffs' FAC alleges that Defendant is directly involved in the CoolSculpting device purchasers' direct and digital marketing of the CoolSculpting procedure, including the direct and inferred representations that the product has FDA approval. Taking these allegations as true, Defendant's Motion should be denied. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (the court need only determine whether the allegations, which taken as true, state a plausible claim); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

For this reason, *Emery v. Visa Int'l Serv. Ass'n*, 95 Cal.App.4th 952 (2002) is inapposite. There, the court found no liability based on unfair business practices where plaintiff "attempt[ed] to ascribe liability for fraud and false advertising based on [defendant's] omission rather than commission." *Id.* at 964. In that case, defendant had no control over the preparation or distribution of certain solicitations, nor did it have any relationship with the merchants that did. *Id.* at 954–55 & 960. This is clearly not the case here where Defendant helped train and prepare marketing practices, and had a direct relationship with merchants touting the

procedure's FDA approval. *Schulz v. Neovi Data Corp.*, 152 Cal.App.4th 86, (2007) (liability may be imposed where the company gives substantial assistance or encouragement to the other in committing the act).

V. PLAINTIFFS' CLAIMS ARE PLEADED WITH THE REQUISITE PARTICULARITY

Defendant argues that Plaintiffs failed to allege with sufficient particularity the deceptive representations that Plaintiffs relied upon in purchasing their CoolSculpting treatments. However, Defendant's argument fails because Plaintiffs specifically plead that Defendant's website, advertisements, and brochures viewed by Plaintiffs make the following specific deceptive claims indicating the FDA's endorsement of the CoolSculpting system:

- "Developed by Harvard scientists, **the CoolSculpting treatment is the only FDA-cleared**, non-surgical fat reduction treatment that uses controlled cooling to eliminate unwanted fat cells."
- "**Cleared by the FDA**, CoolSculpting works by gently cooling targeted fat cells in the body to induce a natural, controlled elimination of fat cells without affecting surrounding tissue, and the treated fat cells are gone for good."
- "In the U.S., **the CoolSculpting procedure is FDA-cleared** for the treatment of visible fat bulges in the submental area, thigh, abdomen and flank, along with bra fat, back fat, upper arms, and underneath the buttocks (also known as banana roll).

(FAC ¶ 7)

The purpose of Rule 9(b) is to provide "defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend

against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985); *see also Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989) ("A pleading is sufficient under Rule 9(b) if it identifies the circumstances constituting fraud so that a defendant can prepare an adequate answer from the allegations"); 5A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1298 (3d ed. 2004) ("Perhaps the most basic consideration for a federal court in making a judgment as to the sufficiency of a pleading for purposes of Rule 9(b) . . . is the determination of how much detail is necessary to . . . enable [an adverse] party to prepare a responsive pleading").

Plaintiffs have clearly met this standard. First, as Defendant points out, Plaintiffs both allege that they "reviewed Zeltiq's official CoolSculpting website, **specifically regarding its representations implying that the device was approved by the FDA.**" (FAC ¶¶ 16, 21) (emphasis added). Not only have Plaintiffs adequately alleged where they saw Defendant's claims but, moreover, Plaintiffs provided specific quotes from Defendant's website alleging exactly what claims they relied upon. Second, Plaintiffs both provide the most recent time period in which they were exposed to Defendant's representations regarding the FDA such that there can be no confusion as to when they visited Defendant's website and reviewed Defendant's advertising materials. (FAC ¶15, "[d]uring the class period alleged herein, and most recently in or around February 2017; FAC ¶20, "[d]uring the class period alleged herein, and most recently in or around March 2017.")

Thus, Plaintiffs have identified more than adequate "circumstances constituting fraud" such that Defendant is aware of the bases for Plaintiffs claims and

can adequately respond.

VI. PLAINTIFFS HAVE PROPERLY ALLEGED ARTICLE III STANDING

Defendant further argues that Plaintiffs are not entitled to injunctive relief because "Plaintiffs are now aware of Zeltiq' allegedly unlawful or misleading conduct" "[n]or have they alleged an intent to purchase CoolSculpting treatments in the future." (Mot. p. 20). Numerous federal district courts have rejected Defendant's arguments and this Court should as well.

As recently stated by Judge Fisher of the Central District of California:

> The purpose of [injunctive relief under the UCL] . . . is to protect California's consumers against unfair business practices by stopping such practices in their tracks…If plaintiffs in false advertising actions are precluded from seeking injunctive relief because by bringing suit they admit knowledge of the alleged falsity, unlawful practices such as those alleged here could never be enjoined, and the purpose of the statute would not be served.

Wilson v. Odwalla, Inc., et al., 2017 WL 3084278, at *3 (C.D. Cal. June 28, 2017).

Other courts have also recognized the absurdity that would result if plaintiffs in these types of cases lacked Article III standing to pursue an injunction.

> It is inconceivable to think prospective relief in the false advertising context is bound by the rules of 'fool me once, shame on you; fool me twice shame on me.' The Court is unwilling to play Defendants' game… This Court will not, as Defendants wish, sound the death knell over California's consumer protection scheme. Defendants' motion to dismiss the injunctive relief claim is denied.

Chester v. TJX Companies, Inc., 2016 WL 4414768, at *8 (C.D. Cal. Aug. 18, 2016). *See, e.g., Cabral v. Supple, LLC*, No. 12 Civ. 85, 2012 WL 4343867, at *2 (C.D. Cal. Sept. 19, 2012) ("While Plaintiffs may not purchase the same . . . products as they purchased during the class period, because they are now aware of the true content of the products, to prevent them from bringing suit on behalf of a

class in federal court would surely thwart the objective of California's consumer protection laws."); *see also Ries v. Arizona Beverages USA LLC*, 287 F.R.D. 523, 533 (N.D. Cal. 2012) ("injunctive relief would never be available in false advertising cases," and calling this "a wholly unrealistic result"); *Henderson v. Gruma Corp.*, 10-cv-04173 AHM (AJWx), 2011 WL 1362188, *18-19 (C.D. Cal. April 11, 2011) (a food labeling case explaining that, under Defendant's argument, "federal courts would be precluded from enjoining false advertising under California consumer protection laws because a plaintiff who had been injured would always be deemed to avoid the cause of the injury thereafter ("once bitten, twice shy") and would never have article III standing"); *Dean v. Colgate-Palmolive Co.*, 2015 WL 3999313, *21 (C.D. Cal. June 17, 2015) ("federal courts would effectively be prohibited from enjoining false advertising under California's consumer protection laws"); *Ackerman v. Coca-Cola Co.*, No. 09 Civ. 395, 2013 WL 7044866, at *15 (E.D.N.Y. July 18, 2013) ("[C]ourts have consistently held that plaintiffs have standing to seek injunctive relief based on the allegation that a product's labeling or marketing is misleading to a reasonable consumer. To hold otherwise would effectively bar any consumer who avoids the offending product from seeking injunctive relief."); *Koehler v. Litehouse, Inc.*, 2012 WL 6217635, *6 (N.D. Cal. Dec. 13, 2012) (same).

Alternatively, at least one court explained that a Plaintiff who is aware of a deceptive label has Article III standing because "there is a likelihood of repeat injury for the class as a whole since some class members do not have the same knowledge as [plaintiff] now does, and on the basis of 'class standing,' the claims may proceed." *Shahinian v. Kimberly-Clark Corp.*, 2015 WL 4264638, *11-12 (C.D. Cal. July 10, 2015).

Litigants filing suit under the UCL, FAL and CLRA must "demonstrate some form of economic injury" to satisfy the requirement of standing pursuant to Article III and the UCL, FAL and CLRA. *See Cardenas v. NBTY, Inc.*, 870 F. Supp. 2d

984, 991 (E.D. Cal. 2012); *Kwikset Corp. v. The Superior Court*, 51 Cal. 4th 310, 323 (Cal. 2011). Plaintiffs can allege economic injury in "innumerable" ways, including by alleging that they paid more in a transaction than they otherwise would have absent the challenged unfair business practice. *Id.* *Werdebaugh v. Blue Diamond Growers*, No. 12-CV-2724-LHK, 2014 WL 2191901, *5 (N.D. Cal. May 23, 2014) ("In cases such as this, both Article III standing and standing under the UCL, FAL, and CLRA can be established by showing the plaintiff either: (1) paid a price premium for a mislabeled product; or (2) would not have purchased the product had he known about the misbranding."); *Stanwood v. Mary Kay, Inc*., 941 F. Supp. 2d 1212, 1218 (C.D. Cal. 2012) ("The harm was not that the product was somehow inferiorly made, but simply that the consumer would not have purchased it at the price he paid, but for the misrepresentations."); *Brazil v. Dole Food Co., Inc.*, 935 F. Supp. 2d at 960–62, 2013 WL 1209955, at *11–13 (holding that plaintiff's allegations that he: (1) purchased products he would not have otherwise purchased had he known the truth about Defendants' "unlawful labeling practices and actions," and (2) paid an "unwarranted premium" due to Defendants' false and misleading labels, satisfied the injury-in-fact requirement for standing at the motion to dismiss stage).

Here, Plaintiffs' allegations fall squarely into the foregoing line of cases. Plaintiffs allege that had Defendant disclosed its knowledge of the lack of FDA approval, they and putative class members "would have paid less for the treatments, declined to purchase the treatments, and/or considered alternative treatments that were FDA-approved." (FAC ¶18, 23, 93). As these allegations more than satisfy the pleading requirements for standing to bring Plaintiff's UCL, FAL, and CLRA claims, it follows that they satisfy the requirements for Article III standing as well. *Hinojos, supra,* 718 F.3d at 1107, n.4. Further, Defendant's second argument here fails as well because both plaintiffs state that they "would consider purchasing CoolSculpting treatments in the future without the price premium." (FAC ¶¶ 19,

24). This is sufficient to indicate an intent to purchase in the future and the likelihood of future injury to Plaintiffs and all class members.

Therefore, the Court should find that Plaintiffs have standing to seek injunctive relief.

VII. CONCLUSION

For these reasons, Plaintiffs respectfully request that the motion to dismiss be denied in its entirety.

Dated: September 1, 2017

Respectfully submitted,

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